

Docket: 187011/US/2

Date of Notice of Allowance: June 9, 2009

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

First Named Inventor:	Lawrence A. Shimp	
Application No.:	10/614,448	Confirmation No.: 7536
Filing Date:	July 7, 2003	Examiner: Srivastava, Kailash
Title:	Method for Sterilizing And/Or Deactivating Adventitious Agents Associated with Biological Materials	Group Art Unit: 1657

**REQUEST FOR RECONSIDERATION OF THE PATENT TERM ADJUSTMENT  
UNDER 37 C.F.R. § 1.705(b)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Applicants/Petitioners have reviewed the Determination of Patent Term Adjustment under U. S. C. 154(b), and hereby request reconsideration based on the following:

As required by 37 C.F.R. § 1.705(b), Applicants provide the following:

(1) The fee set forth in § 1.18(e) of \$200.00.

(2)(i) The correct patent term adjustment is 273 days (587 credit days due to examination delay; 314 debit days due to applicant delay).

(2)(ii) The Patent Office incorrectly calculated 479 days due to Patent Office delay; the correct calculation is 587. The Patent Office issued a first Restriction Requirement on December 30, 2005, however Examiner vacated the Restriction Requirement of December 30, 2005, and issued a new Restriction Requirement on April 17, 2006. A copy of the Restriction Requirement of April 17, 2006, is enclosed herewith as Exhibit A. Accordingly, the period of adjustment of patent term due to examination delay should be counted from September 7, 2004 (14 months from the filing date), to April 17, 2006 (mailing date of the new Restriction Requirement), for a total of 587 days.

(2) (iii) This patent is not subject to terminal disclaimer.

(2) (iv) There are no circumstances constituting a failure to engage in reasonable efforts to conclude processing or examination set forth in 37 C. F. R. § 1.704.

Applicant submits this request with the issue fee, making this a timely request.

Applicants/Petitioners enclose the \$200.00 fee due for reconsideration of patent term adjustment under 37 C. F. R. § 1.18 (e). The Commissioner is authorized to charge any additional fees which may be required, including extension fees, or credit any overpayment to Deposit Account No. 04-1420.

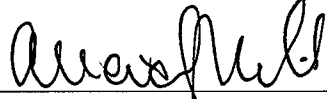
Respectfully submitted,

DORSEY & WHITNEY LLP

**Customer Number 25763**

Dated: Sept. 9, 2009

By:

  
Alicia G. Mills, Reg. No.: 46,933  
Tel.: (612) 340-2755

Enclosure: Exhibit A (Restriction Requirement of April 17, 2006)

EXHIBIT A

ET



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,448	07/07/2003	Lawrence A. Shimp	285-180 PCT CIIP	7536
28249	7590	04/17/2006	EXAMINER	
DILWORTH & BARRESE, LLP 333 EARLE OVINGTON BLVD. UNIONDALE, NY 11553			SRIVASTAVA, KAILASH C	
			ART UNIT	PAPER NUMBER

1655

DATE MAILED: 04/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/614,448

**Applicant(s)**

SHIMP, LAWRENCE A.

**Examiner**

Dr. Kailash C. Srivastava

**Art Unit**

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-88 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-88 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. <u>23/1/2006</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                                     |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____.   |

## DETAILED ACTION

1. Examiner appreciates courtesy extended by the applicant's representative to point out to the Examiner in a telephone interview on 23 January 2006 that the Election Requirement in Office Action mailed 30 December 2005 does not encompass all the claims presented for examination in Applicant's Preliminary amendment filed 09 October 2003.
2. In view of the telephonic interview cited *supra*, Examiner herewith vacates the Election/Restriction requirement in the Office Action of 30 December 2005. A new Office Action follows.

## Claims Status

3. Claims 54-88 are added.
4. Claims 1-3, 6-7, 10-11, 30-31, 33 and 40-43 are amended.
5. Claims 1-88 are pending.

## Election /Restriction

6. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - Group I, consisting of claims 1-10, 24-25, 48-49, 54 and 57-58 drawn to a method to sterilize adventitious agents in a biological material, classified under Class 426, subclass 232, for example.
  - Group II, consisting of claims 1, 11-12 and 44, drawn to a method to sterilize adventitious materials in a biological product with a prepackaging treatment with antioxidants, classified under Class 426, subclass 541, for example.
  - Group III, consisting of claims 1, 11, 13 and 45, drawn to a method to sterilize adventitious materials in a biological product with a prepackaging treatment to remove lipids, classified under Class 435, subclass 366, for example.
  - Group IV, consisting of claims 1, 11, 14-15 and 46, drawn to a method to sterilize adventitious materials in a biological product with a prepackaging treatment to withdraw metal ions with chelation, classified under Class 426, subclass 271, for example.

- Group V, consisting of claims 1, 11 and 16, drawn to a method to sterilize adventitious materials in a biological product with a prepackaging treatment to remove water, classified under Class 34, subclass 284, for example.
- Group VI, consisting of claims 1, 11, 17-23, 47 and 55-56, drawn to a method to sterilize adventitious materials in a biological product with a prepackaging treatment with radiations, classified under Class 426, subclass 248, for example.
- Group VII, consisting of claims 1, 26-29 and 50-51, drawn to a method to sterilize adventitious materials in a biological product, wherein the product is packaged in two packages, classified under Class 426, subclass 106, for example.
- Group VIII, consisting of claims 1, 30, 32-35, 52 and 64-65, drawn to a method to sterilize adventitious materials in a biological product with a prepackaging step to treat the product with an inert gas, classified under Class 426, subclass 312 Or 313, for example.
- Group IX, consisting of claims 1, 30, 61-63, drawn to a method to sterilize adventitious materials in a biological product, wherein the step of creating protective atmosphere for the package comprises exchanging the existing atmosphere with an inert gas and the adventitious agents are one among: bacteria, fungus, mold, prions, virus or yeast, classified under Class 426, subclass 408, for example.
- Group X, consisting of claims 1, 30 and 66-69, drawn to a method to sterilize adventitious materials in a biological product with a prepackaging step to treat the product with an inert gas, wherein the packaged biological material is a donor none, classified under Class 426, subclass 442, for example.
- Group XI, consisting of claims 1, 30, and 70-75, drawn to a method to sterilize adventitious materials in a biological product with a prepackaging step to treat the product with an inert gas and subsequently subjecting said package to any one of the steps to remove one among: lipid, metal ions, water, reducing bio-burden, applying antioxidant or lowering the temperature of the biological material below ambient temperature, classified under Class 426, subclass 426, for example.
- Group XII, consisting of claims 1, 30 and 76-88, drawn to a method to sterilize adventitious materials in a biological product with a prepackaging step to treat the product with an inert

gas and subsequently with an ionizing radiation to reduce the bio-burden of said package, classified under Class 426, subclass 521, for example.

- Group XIII, consisting of claims 1, 31, 36-39, 53 and 59-60, drawn to a method to sterilize adventitious materials in a biological product with a prepackaging step to heat and cool said package and to sterilize said package in said heated or cooled state, classified under Class 426, subclass 412, for example.
- Group XIV, consisting of claims 1, and 40-43, drawn to a method to sterilize adventitious materials in a biological product with irradiation, classified under Class 426, subclass 240, for example.

### **Linking Claims**

7. Claim 1 and 11 link inventions in groups I-VI, while Claims 1 and 30 Link inventions in groups VIII-XII. The restriction requirement between the linked inventions is subject to the non-allowance of the linking claims, identified above. Upon the allowance of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claims are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. §121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131- 32 (CCPA 1971). See also MPEP §804.01.

### **Inventions are Independent and Distinct**

8. The inventions are distinct, each from the other because of the following reasons:

Inventions in Groups I-XIV are unrelated to each other because each one of them is directed to different inventions that are not connected in design, components, operation and/or effect. These inventions are independent since they are not disclosed as capable of use together. They have different modes of operation, they have different functions, and/or they have different effects. One would not have to practice the various methods at the same time to practice just one method alone (MPEP § 806.04, MPEP § 808.01). In the instant case, for example invention recited in claims encompassed in Group II is directed to a method requiring a composition and step that is not required for the method of

Claims encompassed in Group VII method. Thus, the methods in each of the inventions of Group II and VII have a different effect. Therefore, the methods claimed in inventions II and VII for e.g., may not be practiced together. Similarly methods in inventive Groups I, III-VI and VIII-XIV do not have the same components and/ or steps and therefore, each of inventive groups I-XIV will not be practiced together/simultaneously.

The inventions discussed above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each one of the above inventions is not coextensive particularly with regard to the literature search. Further, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification (i.e., Class and subclass), and their recognized diverse subject matter, they would illicit an undue burden on the examiner to search and examine all the inventions in groups I- VI in one single application. Furthermore, the criteria for patentability may not be same for each of the recited groups and what may be applicable for one group may not at all be applicable to other group. Thus, restriction for examination purposes as indicated is proper.

9. Applicants are advised that a reply to this requirement must include an identification of an invention elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicants will be entitled to consideration of additional claims which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR §1.141. Currently, Claim 1 is the only generic claim. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a)

10. Applicants are reminded that upon the cancellation of claims to a non-elected invention, inventorship must be amended in compliance with 37 CFR §1.48(b) Any amendment of inventorship must be accompanied by a petition under 37 CFR §1.48(b) and by the fee required under 37 CFR §1.17(I).


11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner



can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Terry McKelvey, can be reached on (571)-272-0775 Monday through Friday 8:30 A.M. to 5:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). Alternatively, status inquiries should be directed to the receptionist whose telephone number is (703) 308-0196.

 Kailash C. Srivastava, Ph.D.  
Patent Examiner  
Art Unit 1655  
(571) 272-0923

April 10, 2006

  
RALPH GITOMER  
PRIMARY EXAMINER  
GROUP 1200